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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,276	12/21/1999	YOSHIHISA NISHIBE	Q57234	2101

7590 10/09/2002

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,276	NISHIBE ET AL.	
	Examin r	Art Unit	
	Amy E Pulliam	1615	

-- Th MAILING DATE of this communication appears on the cover sh et with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *23* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Notice of Appeal, the Request for a CPA, Preliminary Amendment B, Prior Art with Attachment, and the 132 Declaration, received by the Office December 14, 2001, July 8, 2001, July 8, 2001, July 24, 2002, and August 8, 2002, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, and 5-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,976,573 to Kim. Kim discloses an aqueous pharmaceutical composition for application to the mucosal surface of the nasal cavity (abstract). Kim further teaches that the composition includes water, a medicament, a suspending agent comprising microcrystalline cellulose and carboxymethyl cellulose, as well as polysorbate 80 (c 13, claims 5 and 8). Additionally, Kim teaches that the composition preferably includes an iso-osmotic agent, such as sodium chloride, in order to prevent irritation of the mucosa (c 6, l 50-55).

Kim does not specifically teach the osmotic pressure of their invention. However, it remains the position of the examiner that absent evidence to the contrary, or a showing of unexpected results regarding a particular osmolarity, this limitation is not rendered patentably significant.

Kim does not teach the inclusion of a hemostatic agent, However, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art to include a hemostatic agent in a mucosal formulation, so as to prevent any unwanted bleeding from the surface of the tender mucosal tissue. Absent any evidence to the contrary, the examiner sees no criticality placed on the presence of a hemostatic agent in the formulation. Further, Kim does not teach all of the examples of applicant's claimed osmotic controlling agents or water soluble polymers. However it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any osmotic agent, or water soluble polymer which is known in the pharmaceutical art, based on the teachings of Kim. One of ordinary skill in the art would have been motivated to create an aqueous pharmaceutical composition for mucosal administration comprising an osmotic agent, a drug, a water soluble polymer, a water insoluble substance, a surfactant, and other additives, such as a hemostatic agent, based on the teachings of Kim. The expected result would be a successful and safe mucosal formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found persuasive. Applicant has amended the claims to limit the osmotic pressure to 72 mOsm or less, rather than less than 290 mOsm. Additionally, applicant has submitted additional data and a declaration to further support their invention.

With regards to the declaration of Atsuhiro Nagano, the declaration is not found to be persuasive. Mr. Nagano discloses examples of compositions having osmolarities ranging from 90 to 340 mOsm. The claims, as amended recite osmolarities of 72 mOsm or less. Therefore, the declaration is not commensurate in scope with the limitations of the instant claims, and is found to be unpersuasive.

Applicant also submitted several pages of data explanations. However, the examiner maintains that this data is also not commensurate in scope with the instant claims. Throughout the data, it appears that osmolarities up to 72 do not render the significant increase in bioavailability. Instead, it appears that this increase occurs at an osmolarity between 73 and 30 mOsm, although because there is not data between these two limits, it is impossible to tell where the bioavailability really begins to increase unexpectedly. The examiner maintains her position that the difference between 13% and 16 % bioavaiablity does not show an unexpected result, compared to the difference between 16% and 47 % bioavailability (as shown at page 2 of the attachment, the first tablet, comparing 30, 72 and 128 mOsm).

Additionally, the scope of the instant claims is an osmolarity of less than 72mOsm. However, much of the data presented in the attachment provides examples going as low as 5 mOsm, rather than 0 mOsm. On page 3 of the attacment, there is some data regarding a 0 osmolarity, and this data shows a decrease in the bioavailability lower than an osmolarity of 5 mOsm, however, this is not reflected in the claim language.

Lastly, applicant has stated that the bioavailability of Kim could not be measured. The examiner maintains her position that absent a showing of unexpected results, which is commensurate in scope with the instant claims, Kim's composition would inherently possess all

of the same characteristics as applicant's, because Kim teaches all of the components to applicant's claimed composition.

Applicant has provided no evidence to show that their claimed invention differs from the invention of Kim. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Due to the absence of comparative data, and the lack of evidence commensurate in scope with the instant claims, this instant rejection is maintained. Applicant is urged to provide data which provides evidence regarding the actual ranges claimed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
October 7, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600